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COMPACT COLLAPSIBLE INFUSION APPARATUS

SUC BACKGROUND OF THE INVENTION

5 P The present invention relates to liquid dispensing apparatus and pertains particularly to an improved infusion apparatus for delivering intravenous drugs at a controlled rate to a patient.

10 It is often necessary to intravenously supply patients with pharmaceutically active liquids at a controlled rate over a long period of time. It is desirable that this be accomplished while the patient is in an ambulatory state. A few devices have been developed in the past for accomplishing this purpose.

15 The prior art devices typically comprise an elastic bladder forming a liquid container mounted in an elongated cylindrical housing, and having a flow control valve or device and tubing for supply of the liquid to the patient. These devices are constructed with the cylindrical form in 20 order to provide a compact arrangement. The elastic walls of the bladder are forced to expand along the walls of the cylindrical housing when filled with the liquid, and provide the pressure for expelling the liquid. These prior

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art devices are typically filled by hand by means of a syringe which often require an inordinate amount of force.

Another drawback to the prior art devices is that the bladder is forced to expand into an unnatural elongated configuration along the housing walls as the container is filled. As a result of this unnatural configuration, the pressure of the bladder and the flow rate of the unit varies widely with the volume of liquid therein. Therefore, they do not have a reasonably stable pressure and flow rate over the infusion period.

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LF Prior U.S. Patents 5,080,652, dated January 14, 1992 and 5,105,983, dated April 21, 1992 of common assignment herewith disclose recently developed improved infusion devices. These devices have an inflatable elastic bladder that is allowed or inflate naturally at a substantially uniform pressure. A hard protective housing accommodates natural spherical inflation of the bladder to its rated capacity or volume.

While these improved devices are portable and convenient to use, one objection is that the housing is rigid and space consuming. This increases the cost of packaging, storage and shipment. It also increases the cost of manufacture because the housing must also be

sterilized. Therefore, it would be desirable to have a housing that is collapsible and/or reusable.

It is desirable that the housing of an inflatable bladder infuser be compact and inexpensive to manufacture and ship.

Accordingly, it is desirable that an improved infuser apparatus be available.

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SUMMARY AND OBJECTS OF THE INVENTION

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It is the primary object of the present invention to provide an improved liquid infuser apparatus.

In accordance with a primary aspect of the present invention, a liquid infuser apparatus comprises an elastic reservoir comprising an elastic sleeve mounted on a substantially cylindrical support member mounted within a spherical chamber of a collapsible housing.

Another aspect of the invention includes a protective rigid outer housing in which the infuser apparatus may be removeably placed either in the filled or unfilled condition.

A further aspect of the invention comprises a kit of a plurality of the infusers packaged with a single reusable protective rigid outer housing in a compact arrangement.

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BRIEF DESCRIPTION OF THE DRAWING

P The above and other objects and advantages of the present invention will become apparent from the following description when read in conjunction with the accompanying 5 drawings wherein:

Fig. 1 is a top plan view of a preferred embodiment of the invention;

13 Fig. 2 is a view taken on line 2-2 of Fig. 1;

Fig. 3 is an enlarged detailed view of a portion of 10 Fig. 2 showing the retaining cap and coupling;

Fig. 4 is an enlarged detailed top view of the check valve assembly of the embodiment of Fig. 1;

13 Fig. 5 is a section view taken on line 5-5 of Fig. 4;

Fig. 6 is a side elevation view showing a filled 15 infuser in a rigid housing;

Fig. 7 is a top plan view of a kit embodiment of the invention;

13 Fig. 8 is a section view taken generally on lines 8-8 of Fig. 7;

20 Fig. 9 is a top plan view of a filling jig for use with the invention;

Fig. 10 is a section view taken generally on lines 13 10-10 of Fig. 9;

Fig. 11 is a side elevation view of an alternate embodiment of a rigid housing;

Fig. 12 is a side elevation view of a further embodiment of a rigid housing;

5 Fig. 13 is a perspective view of an alternate shipping package embodiment of the invention; and

Fig. 14 is a top plan view of a combined package and rigid housing embodiment of the invention.

DECL DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

10 Referring to the drawings, and particularly to Figs. 1 and 2, there is illustrated an exemplary embodiment of an infuser pump in accordance with the invention. The infuser pump, designated generally by the numeral 10, is collapsible and comprises an outer collapsible 15 substantially non-stretchable housing or shell 12, protectively mounted over a combined reservoir and support assembly constructed substantially like that set forth in
15 U.S. Patent No. 5,080,652, dated January 14, 1992 and
FB U.S. Patent No. 5,105,983, dated April 21, 1992, both of which are
L incorporated herein by reference as though fully set forth.
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The collapsible housing 12 has a substantially spherical configuration for confining and guiding the inflatable reservoir or bladder into a concentric position around the central support member, and enabling it to

expand naturally in a spherical configuration as will be described. The collapsible housing 12, as been seen in Fig. 2, has coaxial openings defined by tubular sleeve extensions 14 and 16 through which the ends of a central support member 18 extends.

An elastic membrane or bladder assembly 20 forming an inflatable reservoir, such as described in the aforementioned patents, is mounted on the cylindrical support member 18. The bladder assembly 20 may be a single sleeve or multiple sleeves, as set forth in the prior 10 patents. This is preferably with an inner sleeve being a chemically inert sleeve, and the outer sleeve or sleeves being highly elastic.

The central cylindrical support member or mandrel 18 *only one of which, is shown,* 15 *includes circular grooves 22 and 24 at the ends thereof* into which portions of the sleeve 20 and housing 12 are biased by means of a pair of O-rings, only one of which, 26, is shown. The collapsible housing 12 is preferably a non-stretch blow molded housing of from five to ten mils. 20 in thickness and made of a material such as polyurethane, PVC film, and/or polyethylene and is transparent. This forms a simple inexpensive compact unit with a certain amount of protection for the elastic reservoir.

Certain applications may require a tougher collapsible housing. In such cases, the housing should be transparent, UV stable, flexible and highly resistant to puncturing. The housing would be constructed of a material such as tough composites in a flexible form such as a fabric. Examples of such material are available under the trademark Kevelar.

The ends of the central support member 18 include reduced diameter extension 30 and 32, with bayonette type 10 couplings for releasably coupling cup-shaped caps 34 and 36 which extend over and protectively cover the O-ring connections or clamping of the elastic bladder and collapsible housing to the support member. Referring to Fig. 3, the bayonette connection for member 32 and 36 is 15 illustrated. The member 32 has flat sides 38 for receiving a similarly shaped opening 40 in cap 36, with the cap 36 having inwardly extending flanges forming the flat sides which extend behind shoulders of the extension 32 for retaining the cap in place upon rotation of the cap ninety 20 degrees relative to the member 32. This forms a quick and easy assembly construction for the protective cap.

The support member 18 has an inlet or fill port 42 on one end which communicates with a coaxial passage 44, and a transverse passage 46 in which is mounted a check valve

48. The cross bore 46 communicates with passage 44 and inlet port with the interior of the elastic bladder or sleeve ²⁰ ~~22~~ and thus the interior of the inflatable reservoir. The check valve 48 (Figs. 4 and 5) is of a generally cylindrical outer shape, with a square bore 50 extending from one end and closed at the other forming a cup-shaped structure. The check valve is constructed of an elastomer, such as silicone, and collapses inward to allow filling and erects to its normal configuration to prevent back flow. The square bore configuration of the bore insures that it returns to its normal configuration and does not remain collapsed.

An outlet port through end 32 communicates with a passage 54 that extends coaxially from the other end of the support member 18, and communicates with a cross bore or port 56 with the interior of the elastic bladder or reservoir 20. A tubing set, including a tube 52 having a filter 58 and a connector 60 at the end, provides a means for connecting and dispensing a fluid to a site, such as a vein of a patient.

The collapsible infuser apparatus of Figs. 1 and 2 comprises a compact and inexpensive disposable unit. It has a compact configuration, with a collapsed diameter no greater than the outer diameter of the caps 34 and 36. For

this reason, it is convenient to package in multiple unit kits as will be subsequently described. In addition, it may be temporarily housed during use in a protective hard shell housing as illustrated in Fig. 6.

5 Referring to Fig. 6, a simple exemplary protective housing 62, in the illustrated embodiment, having a generally cylindrical configuration with an open top and a diameter, can receive and accommodate the fully expanded or filled reservoir during use. This provides a reusable
10 protective housing that may be provided with a kit of multiple infuser units. The protective housing is preferably formed of a high strength material such as polycarbonate. The filled infuser may be placed in the protective housing 62 and placed in a carrying pouch, thereby providing protection against accidental undue
15 pressure or accidental puncturing of the reservoir bladder. The inflatable bladder or reservoir is very susceptible to puncturing when in the inflated condition. For this reason, it is desirable that it be within a
20 puncture resistive housing when inflated. The housing 62 may have other configurations and may have a removable cover if desired (see Figs. 11 and 12).

Referring to Figs. 7 and 8, a kit of multiple infusers, in accordance with the invention, is packaged as

a kit for convenient use for a seven day period, for example. As illustrated in Figs. 7 and 8, the kit comprises a generally rectangular opened top box or container 64 of a very thin, substantially rigid plastic material having a peripheral flange 66 for attachment of a suitable cover. The container forms a chamber in which is placed a styrofoam support block 68 having a plurality of bores 70 spaced around the periphery thereof for receiving the inlet end and cap portion of a plurality of the infusers 10.

A cylindrical bore 72 in the center of the block 68 receives the cylindrical housing 62 in an upright position. Positioned within the housing 62 is a circular or cylindrical styrofoam block 74 having three bores 76 similar to the bore 70 for receiving the filler ends of three infusers 10. This provides a kit of seven infuser units providing a week's supply.

These kits are easily packaged at a factory and shipped to a hospital or to a pharmacist who removes and fills the infusers and supplies them along with a reusable housing 68 to a patient for home use. The patient then uses each of the infusers in consecutive order and disposes of them when used. This provides a compact convenient package. The package has a typical size of approximately 4

174B182 1/4 inches high and 3 3/4 inches on a side. This takes up slightly more than the space of a single unit of the prior design having a hard shell. For example, a one-hundred B milliliter hard shell unit is about 4 inches in length and 54178 about 2 1/2 to 3 inches in diameter. Thus, a package of seven of the present units takes about sixteen cubic inches of space versus about twelve cubic inches for one of the prior units.

Referring to Figs. 9 and 10, a convenient filling rack 10 for an infuser of the present design is illustrated, designated generally by the numeral 78. The rack is molded of a suitable plastic material and is formed within the illustrated embodiment with 7 (or any other suitable number) identical holder positions. Each holder position 15 has a central cavity 82 for receiving and enabling expansion of the bladder, an upper recess 84 for receiving a filler end cap 34, and a lower recess 86 for receiving a cap 36. The panel 80 has a forward leg 88, with a foot 90 to hold the support panel in an included position for ease 20 of use. The pharmacist may simply load the rack with a plurality of infusers and either fill them in sequence or simultaneously as desired.

Referring now to Fig. 11, an alternate embodiment of an outer housing or shell is illustrated and designated

generally by the numeral 92. This outer housing has a somewhat spherical configuration with outer spherical walls 94 and a lower end which may have an opening 96 for exposing an inlet or fill port 42 for filling. A removable 5 cap 98 provides a closure for an opening 100 in the top of the housing. The cap includes a central opening 102 for extension of a tubing set 58. The cap 98 may be attached in any suitable manner such as friction fit, bayonette type coupling, threads or the like to the housing.

10 The opening 100 in the upper end of the housing walls may be sufficiently large to enable a filled infuser unit, as disclosed in Figs. 1 and 2, to be inserted into the housing. This provides a reusable housing which may also include a cap or closure for protectively closing the 15 unit. In addition, this provides a housing in which the unit without a protective collapsible housing may also be enclosed or housed for filling. In other words, with this unit the collapsible housing 12 of the Figs. 1 and 2 unit may be eliminated. This provides an alternate compact 20 arrangement wherein multiple compact units may be packaged with a single protective outer housing, and provided to a pharmacist for filling and supplying to patients.

Referring to Fig. 12, an openable spherical shell embodiment of a protective housing is illustrated and

designated generally at 100. The housing is constructed of two identical half-shells 102 connected together by a hinge pin 114. Thus, a filled or unfilled infuser may be placed in the reusable protective housing. The shells each have 5 an opening 116 and 118 at each end with an inwardly spaced wall 120 and 122, each having an opening 124 and 126. The end caps 34 and 36 of an infuser are received in the openings 116 and 118, and the central support member 18 is received in the openings 124 and 126. The ends of the 10 infuser unit are thereby exposed for access. The hinge axis extends along a line parallel to an axis defined by the openings in the shell.

Referring to Fig. 13, an alternate embodiment of a packaging system for multiple infusers is illustrated and 15 designated generally by the numeral 128. A base container sheet 130 has a plurality of cavities 132 formed therein for receiving infuser units 10. A cover sheet 134 covers the base sheet and cavities to protectively seal the infuser units in the cavities. The base sheet may be 20 either flexible or somewhat rigid. The base sheet and cover sheet have perforations 136 separating the cavities 132. This enables selective separation of single units from the overall package. Alternatively, the entire cover

sheet can be peeled away to provide common access to a plurality of the infuser units.

Referring to Fig. 14, an alternate embodiment of combined packaging and protective housing is illustrated.

5 This package, designated generally by the numeral 104, comprises opposed thin plastic sheets, only one of which 106 is shown, forming mirror images of one another. These opposed sheets have semi-spherical recesses or cavities forming a generally spherical chamber in which a dispensing 10 unit 10, substantially as described in Figs. 1 and 2, is encapsulated, with an opening or bore 108 through which a filler port or cap 42 extends. The package also provides an opening 110 at the other end for extension of a tubing set 58. The entire package can contain any selected number 15 of units which may be shipped to a pharmacist. The pharmacist may take the package and select and separate an appropriate number of the infusers, fill them and supply them to a patient. The infuser units may be separated along a perforated line 112 of the package such that an 20 individual infuser may be separated from the remainder.

Thus, the unit of Fig. 1 can be effectively packaged in simple and inexpensive packaging for supplying to pharmacists. This form of packaging can also be used without the collapsible housing, such that the unit

contains only the inflatable reservoir, and the packaging forms a protective non-collapsible housing. Similarly, the units without the collapsible housing can be used with any of the rigid housings discussed herein.

5 While we have illustrated and described our invention by means of specific embodiments, it is to be understood that numerous changes and modifications may be made therein without departing from the spirit and scope of the invention as defined in the appended claims.

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WE CLAIM: